



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,804	04/17/2001	Gebre-mariam Mesfin	6267.N	6782

7590 01/29/2003

Andrew M. Solomon
Pharmacia & Upjohn Company
Global Intellectual Property
301 Henrietta Street
Kalamazoo, MI 49001

EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,804

Applicant(s)

MESFIN ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 12, 2002 has been entered.

This Office Action is a response to Applicant's request for continued examination (RCE) filed November 12, 2002 in Paper No. 11, and amendment and response to the Final Office Action (mailed July 2, 2002), filed November 12, 2002 in Paper No. 12 wherein claims 1-12 have been amended. Currently, claims 1-12 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to the methods for preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Nature of the invention: The instant invention pertains to the method for preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

The state of the prior art: The skilled artisan would view that the treatment to prevent osteoporosis, bone resorption, or other bone disease in a vertebrate mammal is highly unlikely.

The predictability or lack thereof in the art: The skilled artisan would view that the treatment to prevent osteoporosis, bone resorption, or other bone disease in a vertebrate mammal is highly unpredictable.

The presence or absence of working examples: In the instant case, no working examples are presented in the specification as filed showing how to prevent osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Therefore, in view of the Wands factors, as discussed above, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art, Applicants fail to provide information sufficient to practice the claimed invention.

Applicants are suggested to delete "preventing" in the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "other bone disease" in claims 1 and 7 renders claims 1-12 indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. The expression "other bone disease" is not defined in the specification. Therefore, the scope of claims is indefinite as to the methods encompassed thereby.

Claims are indefinite for reciting "characterized by" in claims 1 and 7, failing to conform with current US practice. Therefore, the scope of the claims is indefinite.

Applicants are suggested to delete "characterized by" in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batts et al. (WO 9925344, PTO-892).

Batts et al. discloses that the instant active compounds are useful in methods for treating arthritis in a patient. Batts et al. also discloses that the instant active compounds are administered in the instant range orally and/or parentally. Batts et al. further discloses methods of manufacture of the instant compounds. See abstract, page 1 lines 33-36, page 4 lines 31-36, page 12, Example B, line 13-23 therein.

Batts et al. does not expressly disclose the employment of the instant active compounds in a method of treating osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating or osteoporosis, bone resorption, or other bone disease in a vertebrate mammal because active compounds herein are known to be useful in methods for treating arthritis in a patient according to Batts et al. Arthritis are known to be tightly associated with bone diseases, to induce bone destruction, and to stimulate bone matrix loss. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known to treat arthritis would have beneficially therapeutical effect on the treatment of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. of record stated in the Office Action dated July 2, 2002.

Hester et al. discloses that the instant active compounds as being antibacterial agents are useful in pharmaceutical compositions and methods for treating or combating bacterial infections in animals. Hester et al. also discloses that the instant active compounds are administered in the instant range orally and/or parentally. Hester et al. further discloses methods of manufacture of the instant compounds. See abstract, page 32 line 27 to page 33 line 13, page 42-81, page 109 lines 24-27 and claim 3 therein.

Hester et al. does not expressly disclose the employment of the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Nair et al. teach that bacteria are important cause of bone diseases and induce bone destruction, and many bacteria are capable of stimulating bone matrix loss. See title and abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating or

preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal because active compounds herein are known antibacterial agents and known to be useful broadly in methods for treating or combating bacterial infections in animals according to Hester et al. Bacteria are known to be important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss according to Nair et al. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutical effect on the treatment or prevention of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al. of record stated in the Office Action dated July 2, 2002.

Yoshida et al. discloses that active compounds therein within the instant claim as antibacterial agents exhibit excellent antibacterial activity. Yoshida et al. further discloses methods of manufacture of the instant compounds. See abstract.

Yoshida et al. do not expressly disclose the employment of the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. Yoshida et al. do not also disclose that the instant active compounds are administered in the instant range orally and/or parentally.

Nair et al. teach that bacteria are important cause of bone diseases and induce bone destruction, and many bacteria are capable of stimulating bone matrix loss. See title and abstract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal, and to administer the active compounds herein in the instant range orally and/or parentally.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant active compounds in a method of treating or preventing osteoporosis, bone resorption, or other bone disease in a vertebrate mammal because active compounds herein are known antibacterial agents and known to exhibit excellent antibacterial activity in animals according to Yoshida et al. Bacteria are known to be important cause of bone diseases, to induce bone destruction, and to stimulate bone matrix loss according to Nair et al. Therefore, one of ordinary skill in the art would have reasonably expected that the instant compounds known as antibacterial agents would have beneficially therapeutical effect on the treatment or prevention of osteoporosis, bone resorption, or other bone disease in a vertebrate mammal. Additionally, one of ordinary skill in the art would have been motivated to administer the active compounds herein in the instant range orally and/or parentally since the optimization of amounts of active agents to be administered and determination of routes

of administration from those well known in the art is considered well within the skill of artisan, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Applicant's remarks filed on November 12, 2002 in Paper No. 12 with respect to the rejection made under 35 U.S.C. 103(a) as being unpatentable over Hester et al. (WO 9854161) in view of Nair et al. and the rejection made under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (WO 9912914) in view of Nair et al., in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that osteoporosis or bone resorption are not reported to have a bacterial basis in the cited references. However, the instant base claims and other dependent claims, 1-5 and 7-11, read on the treatment of any osteoporosis, bone resorption, or other bone disease in a vertebrate mammal, including the bone diseases associated with bacteria.

As discussed in previous Office Action July 2, 2002, Applicant's results on "Use of Compounds" of the specification at pages 44-45 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive for the reasons below. The example herein merely demonstrate the employment of one particular compound within the instant claims in the treatment for increasing bone mass and density. Thus, the

Art Unit: 1617

evidence in the example is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the active compounds in the claimed methods of treating various bone diseases herein. See MPEP § 716.02(d). Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

Applicants are suggested to amend the instant claims, i.e., administering to a vertebrate mammal having specific bone diseases in need thereof, in order to clearly distinguish over the methods of the treatments in the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Application/Control Number: 09/836,804
Art Unit: 1617

Page 12

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
January 22, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER
1/26/03